REMARKS

Nature of the Problems Solved by the Present Invention

The problems addressed by the present invention include:

1) to create solid dosage forms comprising active ingredients, e.g., tablets or pellets, that are voluntarily taken by animals, i.e., that are highly palatable;

2) to reduce the release of bad tasting active ingredient during mastication of the tablets or pellets comprising animal feed material and active ingredient, so that uptake by animals is increased and is more reliable; and

3) to prevent the loss of activity of the active ingredient during processing and storage when mixed in intimate contact with organic material of animal or vegetable origin, i.e., when compressed together with such materials in a tablet or pellet as animal feed.

See Applicants' specification, e.g., at the paragraph spanning pages 4 and 5.

The inventors have provided a solution that eliminates or reduces the negative consequences of such problems by providing *a pellet or tablet* comprising 1) an animal feed substrate and 2) coated particles, where the coated particles include a) a carrier material, coated with b) a casing comprising an active ingredient, and c) a masking protective layer coating the casing.

The primary reference addresses a problem that is unrelated to those noted above. Further, all of the references cited fail to consider the problems addressed by the present invention.

Commercial Success

An important embodiment of the present invention shows enormous commercial success directly linked to the patentable features as presently claimed. FORTEKOR, by Novartis Animal Health, is a very successful commercial product representing one embodiment of the presently claimed invention. FORTEKOR leads strongly amongst ACE (angiotensin converting enzyme) inhibitors in Europe, and it is the leading ACE Inhibitor for dogs in every market (~50% market share overall). Sales of FORTEKOR have shown steady and consistent growth (e.g., 10% in 2006).

FORTEKOR is the only product licensed for treatment of renal failure in cats and it is accepted as standard therapy, particularly for cats with proteinuria. FORTEKOR's commercial success is based significantly on the innovative, highly palatable formulation. The formulation, in accordance with the presently invention, significantly enhances acceptance by the pet and is the key for client compliance.

Novartis has conducted a palatability test with a large sample size (212 client-owned, healthy cats) that clearly proved that the FORTEKOR tablet is a real breakthrough with regard to oral cat treatment. Pages 16 to 18 of Applicants' specification, as published in the international parent application, provide a qualitative discussion comparing the results with cats using the present invention relative to other attempts to solve the problem. The link between the patentable features of the presently claimed invention and the commercial success of FORTEKOR is strong.

Rejection under 35 U.S.C. § 103 is Traversed

Patel in view of Jones, Friedman, Malnoe, or Alford

The Examiner rejected claims 21, 22, 24-30, and 32-36 as allegedly unpatentable over WO 03/37808 (Patel) in view of Jones, L.M., Veterinary and Pharmacological Therapeutics, 2nd Edition, The Iowa State Press, Ames, Iowa, pp. 832-834 (1957) (Jones); US Pat. No. 3,824,233 (Friedman); WO 02/071874 (Malnoe), or US Pat. No. 3,937,825 (Alford). Also, the Examiner apparently intended to include US Pat. No. 3,231,466 (Hoffman) as a cited secondary reference, and Applicants have responded accordingly. Based on the following remarks, Applicants respectfully traverse the rejection.

Patel fails to teach or suggest any pellet or tablet formed by intimate mixture of 1) an animal feed substrate with 2) coated particles that are made up of a) a carrier coated with b) an active ingredient and c) covered by a protective masking layer as presently claimed. Because Patel fails to mention any mixture of the compositions described therein with animal feeds, there is absolutely no recognition of the problem solved by the present invention or any teaching or suggestion thereof.

Jones fails to cure the deficiencies of Patel. The references in the cited pages to animals being "fed" antibiotics or the "supplementation of feed with antibiotics," e.g., on page 833, fail to teach or suggest any "dosage forms" or specific "modes of delivery" as asserted by the Examiner

on page 2 of the Office Action. Jones does not teach or suggest that any problem may exist with either refusal of animals to consume the compositions or degradation of active ingredients when in contact with the feed materials.

Similarly, the Examiner asserted that Friedman disclosed "dosage forms and modes of delivery," citing the "top" of column 11 of the patent. The paragraph appearing at the top of column 11 of Friedman is reproduced below:

> My compounds may also be orally administered in the drinking water or feed of the animals to be treated for helminthiasis. Administration in drinking water is accomplished by mixing the proper amount of desired phenylhydrazone into the amount of water which the animal to be treated consumed in a day. Most conveniently, a suspendable composition such as was described for use as a drench is prepared and mixed into the drinking water.

Friedman, col. 11, lines 1-8. Accordingly, it does not appear that Friedman teaches or suggests any dosage forms or modes of delivery in a manner relevant to the present invention or in a manner that would motivate any combination of any teaching therein with any alleged teaching of Patel.

Regarding Malnoe, the Examiner asserted that the reference discusses "dosage forms and modes of delivery . . . for pet food vitamins, with yeast as a part of the pet food." Office Action at page 2, citations omitted. In the cited passages of Malnoe, Applicants note that page 4 fails to disclose any dosage forms or modes of delivery, although it seems to imply that "food compositions" are involved that may comprise an antioxidant. However, there appears to be no description of *how* the antioxidant is present in the "food composition." At the top of page 9, Malnoe indicates that "probiotic micro-organisms," such as yeasts (live yeast *cells*), can be included in pet food and may be encapsulated. Again, Applicants do not understand how this general disclosure could possibly suggest any combination of any teaching therein with any asserted teaching of Patel. The mention of an antioxidant in a food composition does not include any teaching of suggestion of dosage form or mode of delivery, counter to the Examiner's assertion. The mention of the possibility of including encapsulated yeast cells in pet food as probiotic microorganisms fails to teach or suggest any relevant aspect of the presently claimed invention and provides no motivation to combine any teaching therein with any alleged teaching of Patel.

Regarding Hoffman, Applicants note that the cited passages are as follows.

From the portion of col. 4 that appears to be intended (emphasis added):

> While this composition may be used as a concentrate for addition to feeds in amounts of , e.g., 2 to 10 pounds per ton, *it has surprisingly been found that the concentrate itself may be safely placed before animals such as swine and cattle for vountary [sic voluntary] free-choice consumptions with effective administration*, in spite of the fact that it has a blue-black color not generally associated with feed-stuffs. Moreover, the animals have been found to have an inherent natural instinct which prevents them from an overdose of the concentrated active ingredients. For poultry, free-choice medication is desirably provided by admixture of the concentrate with, e.g., about 75 to 98% of dry nutrient, preferably dry milk solids such as dry whey, to provide a relatively highly concentrated composition effective in voluntary administration of the active ingredients.

From the bottom of col. 6, immediately following the tabular data (the partial sentence at the end of the column is included for the sake of completeness):

> The ingredients of the composition are thoroughly blended to form a homogenous, free-flowing mixture, the usual procedures for incorporating minor amounts of active ingredients in the mix being employed.
>
> In order to facilitate blending and free flow as well as to provide nutritional value to the composition, dry sea kelp has been used in the composition. This material provides may of the trace elements in minute quantities in organically available form, and its texture facilitates free flow. The starch also promotes better flow and

Based on the passages quoted above, it is Applicants' position that Hoffman's mere mention of mixing of some active ingredients with animal feed provides nothing that would suggest a combination of any teaching therein with any asserted teaching of Patel to obtain Applicants' invention. In fact, Hoffman specifically notes in the passage from column 4 that the animals will take the composition being discussed by "voluntary free-choice consumption." No problems with consumption or palatability, as described and solved by Applicants, are discussed. Accordingly, for at least the reason that Hoffman relates to a composition that is voluntarily consumed by animals without any mixing with feed or particular dosage form or mode of administration, one of ordinary skill in the art would have found absolutely no motivation in Hoffman to combine any teachings therein with Patel.

Regarding Alford, the paragraph containing the passage cited by the Examiner is reproduced below:

> The composition of this invention may be administered orally, or may be injected intravenously, subcutaneously, or intraperitoneally. Oral administration

> may be in the form of (1) a powder that can be mixed in the feed, (2) a bolus administered by means of a balling gun, (3) a mixture either dissolved or dispersed in water and administered by means of a stomach tube or drench, (4) a dose syringe such as used to administer a paste, and (5) a mash or pelleted feed formulation.

Alford, col. 2, lines 18-24. Similar to the other secondary references, Alford fails to teach or suggest the presently claimed invention and does not provide any illustration of the problems solved by the present invention or any motivation to combine any teaching therein with any alleged teaching of Patel.

The Examiner appears to have cited the secondary references for the general proposition that medicinal/nutritional active ingredients may be mixed with feed materials for consumption by animals. Apparently, the Examiner believes that one of ordinary skill in the art would have been motivated to combine this general teaching with teachings found in Patel to obtain Applicants' claimed invention. This is not the case.

Patel relates to a composition developed to provide assertedly, more rapid, sustained, and complete solubilization on administration to a patient. See objects of the invention listed at pages 2 and 3 of Patel. Patel does not teach or suggest anything even implying the inclusion of any such compositions in a feed pellet or tablet. Patel appears to be concerned only with compositions as would normally be intended for administration to humans, i.e., as a typical pharmaceutical dosage form. In this regard, Applicants request that the Examiner review the discussion contrasting factors affecting administration of such compositions to humans and those affecting administration to animals provided by Applicants in their specification, e.g., at pages 1 and 2. Patel fails to teach or suggest the problem described and solved by Applicants in the present invention.

Applicants are well aware of the fact that medicinal compositions have been provided to animals in feed stuffs. However, more than this is required to teach or suggest a combination of the primary reference with any teaching of the secondary references. Although the cited secondary references make mention of some active ingredients provided in animal feed, none of the references recognize the problems solved by the present invention. Accordingly, they fail to provide any motivation for one of ordinary skill in the art to combine any teaching of the references or to modify any teaching of Patel in order to obtain the present invention.

Patel discusses a variety of compositions that were apparently developed to purportedly provide more rapid, complete, and sustain solubilization of pharmaceutically active ingredients in the digestive tract of mammals, preferably a human. Very specific compositions are disclosed in some embodiments. All, however, are disclosed as solutions to the problems of rapid, complete, and sustained solubility in the digestive tract of the mammal to which they are administered. The compositions set forth are disclosed as specialized compositions having desirable characteristics for this purpose. *Any asserted "motivation to combine" any teachings of Patel with any general teaching of the secondary references would have to provide motivation to combine the specific compositions of Patel with those general teachings. No such motivation can be found in any of the references.* The general idea of mixing medicinal or active nutritional substances with animal feed would not lead one of ordinary skill in the art to combine such general teachings with any specialized compositions of Patel in order to obtain Applicants' claimed invention. Should the Examiner maintain the rejection, Applicants respectfully request that he set forth additional details regarding any alleged motivation to combine teachings of the references.

Nothing in the cited references would have suggested combining any specific teaching of the primary reference with the general notion in the secondary references of providing medication in conjunction with feed (as noted above, one of the secondary references even notes that the composition discussed is readily taken voluntarily by the animals in question). One of ordinary skill in the art would not have been motivated to combine any teaching of the references in order to obtain the present invention.

At the beginning of the Remarks section of this paper, Applicants have provided a summary of the problems solved by the present invention and information illustrating the commercial success of a product that is an embodiment of the presently claimed invention. As the Examiner is aware, commercial success is an important secondary indicia of nonobviousness. Where the commercial success of an embodiment of the invention is closely linked to the novelty of the claimed invention and the problem to be solved is not taught in the cited references, a rejection based on alleged obviousness is unsupportable.

In this case, the noted level commercial success indicates that the required motivation to combine any teachings in the art to arrive at the claimed invention would have been lacking prior to Applicants' specification. The Examiner has used impermissible hindsight based on his

reading of Applicants' specification in order to assert that the claimed invention would have been obvious in view of the cited art.

Accordingly, especially in view of the commercial success of the present invention represented by the product FORTEKOR, the rejection based on alleged obviousness should not be maintained. Applicants respectfully request that it be reconsidered and withdrawn.

CONCLUSION

Applicants believe that all rejections have been properly traversed and that all claims are in condition for immediate allowance. If any action other than allowance of all claims is contemplated, Applicants respectfully request that the Examiner contact their undersigned representative to discuss a possible interview prior to issuance of any further official action.

Respectfully submitted,

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